### FDA Facts: Food from Genetically Engineered Plants

#### 1. What is genetic engineering?

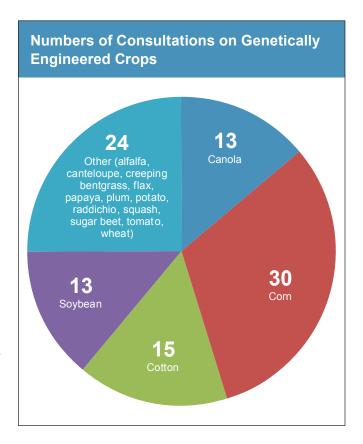
Genetic engineering is the name for certain methods that scientists use to introduce new traits or characteristics to an organism. For example, plants may be genetically engineered to produce characteristics to enhance the growth or nutritional profile of food crops. While these technique are sometimes referred to as "genetic modification," FDA considers "genetic engineering" to be the more precise term. Food and food ingredients from genetically engineered plants were introduced into our food supply in the 1990s.

#### 2. Are foods from genetically engineered plants regulated by FDA?

Yes. FDA regulates the safety of foods and food products from plant sources including food from genetically engineered plants. This includes animal feed, as under the Federal Food, Drug, and Cosmetic Act, food is defined in relevant part as food for man and other animals. FDA has set up a voluntary consultation process to engage with the developers of genetically engineered plants to help ensure the safety of food from these products. FDA regulates genetically engineered animals in a different way. View more information on how FDA evaluates GE animals.

### 3. Are foods from genetically engineered plants safe?

Foods from genetically engineered plants must meet the same requirements, including safety requirements, as foods from traditionally bred plants. FDA has a consultation process that encourages developers of genetically engineered plants to consult with FDA before marketing their products. This process helps developers determine the necessary steps to ensure their food products are safe and lawful. The goal of the consultation process is to ensure that any safety or other regulatory issues related to a food product are resolved before commercial distribution. Foods from genetically engineered plants intended to be grown in the United States that have been



evaluated by FDA through the consultation process have not gone on the market until the FDA's questions about the safety of such products have been resolved.

#### 4. How is the safety of food from a genetically engineered plant evaluated?

Evaluating the safety of food from a genetically engineered plant is a comprehensive process that includes several steps. Generally, the developer identifies the distinguishing attributes of new genetic traits and assesses whether any new material that a person consumed in food made from the genetically engineered plants could be toxic or allergenic. The developer also compares the levels of nutrients in the new genetically engineered plant to traditionally bred plants. This typically

includes such nutrients as fiber, protein, fat, vitamins, and minerals. The developer includes this information in a safety assessment, which FDA's Biotechnology Evaluation Team then evaluates for safety and compliance with the law.

FDA teams of scientists knowledgeable in genetic engineering, toxicology, chemistry, nutrition, and other scientific areas as needed carefully evaluate the safety assessments taking into account relevant data and information.

FDA considers a consultation to be complete only when its team of scientists are satisfied with the developer's safety assessment and have no further questions regarding safety or regulatory issues. Please see http://www.fda.gov/bioconinventory for a list of completed consultations.

## 5. Why do developers genetically engineer plants and which has FDA evaluated for safety?

Developers genetically engineer plants for many of the same reasons that traditional breeding is used, such as resistance to insect damage, hardiness or enhanced nutrition. As of December 2012, the FDA has completed 95 consultations, most of them on corn. The chart below shows the number of consultations completed as of April 1, 2013 for each of the genetically engineered plants FDA has reviewed. There were 30 submissions on corn, 15 on cotton, 12 each on canola and soybean, and 24 on all other crops including alfalfa, canteloupe, creeping bentgrass, flax, papaya, plum, potato, raddichio, squash, sugar beet, tomato, and wheat.

Numbers of Consultations on Genetically Engineered Crops: 30 submissions on corn, 15 on cotton, 12 each on canola and soybean, and 24 on all other crops including alfalfa, canteloupe, creeping bentgrass, flax, papaya, plum, potato, raddichio, squash, sugar beet, tomato, and wheat

#### 6. Which foods are made from genetically engineered plants?

The majority of genetically engineered plants - corn, canola, soybean, and cotton - are typically used to make ingredients that are then used in other food products. Such ingredients include cornstarch in soups and sauces, corn syrup as a general purpose sweetener, and cottonseed oil, canola oil, and soybean oil in mayonnaise, salad dressings, cereals, breads, and snack foods.

### 7. Are foods from genetically engineered plants less nutritious than comparable foods?

Nutritional assessments for foods from genetically engineered plants that have been evaluated by FDA through the consultation process have shown that such foods are generally as nutritious as foods from comparable traditionally bred plants.

# 8. Are foods from genetically engineered plants more likely to (1) cause an allergic reaction or (2) be toxic?

The foods we have evaluated through the consultation process have not been more likely to cause an allergic or toxic reaction than foods from traditionally bred plants. When new genetic traits are introduced into plants, the developer evaluates whether any new material could be (1) allergenic or (2) toxic if consumed in foods made from the genetically engineered plants or from ingredients derived from these plants.

#### 9. Why aren't foods from genetically engineered plants labeled?

We recognize and appreciate the strong interest that many consumers have in knowing whether a food was produced using genetic engineering. Currently, food manufacturers may indicate through voluntary labeling whether foods have or have not been developed through genetic engineering, provided that such labeling is truthful and not misleading. FDA supports voluntary labeling that provides consumers with this information and has issued draft guidance to industry regarding such labeling.

#### 10. Are there long-term health effects of foods from genetically engineered plants?

When evaluating the safety of food from genetically engineered plants, scientists with experience in assessing the long-term safety of food and food ingredients consider several factors, such as information about the long-term safety of the food from traditionally bred crops in combination with information on the food safety of the newly introduced traits. Foods from genetically engineered plants that have been evaluated by FDA through the consultation process have not gone on the market until the FDA's questions about the safety of such products have been resolved.

April 7, 2013